UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

~~DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION~~

DP BARCODE No.: D440281; **FILE SYMBOL No**.: 83529-TT; **PRODUCT NAME**: Sharda Fluroxypyr (MHE) 15.3% + Dicamba 12.0% EC; **DECISION No**.:527160; **PC Code(s)**: 128931 & 128968; **ACTION CODE**: R300; **FOOD Use**: Yes; **COMPANY:** Sharda USA LLC

DATE OUT: June 1, 2017

SUBJECT: End Use Product Chemistry Review
Product Name: Sharda Fluroxypyr (MHE) 15.3% + Dicamba 12.0% EC

FROM: Shyam Mathur, Ph. D
Team Leader
Chemistry, Inerts & Toxicology Assessment Branch (CITAB) /RD (7505P)

TO: Bethany Benbow / Kathryn Montague, RM 23; Herbicide Branch / RD (7505P)

INTRODUCTION:

The registrant has submitted an application for the registration of the new end use product Sharda Fluroxypyr (MHE) 15.3% + Diglycoamine salt of Dicamba 12.0% EC. The registrant has submitted a CSF for basic formulation dated March 28, 2017 and the supporting group A & group B product chemistry data with MRID No(s). 50194801 to 50194807. The registrant has claimed that the proposed product is substantially similar to the registered product with Reg. No. 100-1343. On the advice of the Agency, the registrant has submitted the revised basic CSF (dated 06-01-2017). CITAB has been asked to determine the acceptability of the proposed revised basic CSF, the supporting product chemistry data and also determine similarity to the registered product.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Fluroxypyr MHE (15.30%) and Diglycoamine salt of Dicamba (12.0%)

2. Has the registrant claimed substantial similarity to a registered product?

   [X] Yes; [ ] No; [ ] NA; if yes give the registration number of the cited product.

   EPA Reg. No: 100-1343

3. All of the source materials of the active ingredient are derived from registered sources- [X] Yes [ ] No

4. All inert ingredients have been screened by CITAB (Inert group) and found to be approved for the proposed labeled uses.

5. Confidential Statement of Formula(s):

   [X] Basic - Dated: 03-28-2017; Re-submitted - Dated: 06-01-2017

   [ ] Alternate CSF – All Dated: ; Re-submitted alt CSF – Dated:

   Alternate CSF(s) complies with 40CFR§152.43: [ ] Yes; [ ] No; [X] NA

6. Product label

   a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).
   [X] Yes; [ ] No; if not, explain below:

   Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)
   [X] Yes; [ ] No; if not, explain below:

Metallic equivalent:	[ ] Yes [X] NA	
Soluble arsenic:	[ ] Yes [X] NA	
Isomeric ratios:	[ ] Yes [X] NA	
Acid Equivalent:	[X] Yes [ ] NA:	Dicamba acid equivalent = 8.13% (0.93 lbs/gal) Fluroxypyr acid equivalent = 10.62% (0.71 lbs/gal)

   b. Health related sub statements: Product contains?

Petroleum distillate at > 10%:	[ ] Yes	[X] No	[ ] NA
Methanol at > 4%:	[ ] Yes	[X] No	[ ] NA
Sodium nitrate/Sodium nitrite	[ ] Yes	[X] No	[ ] NA

   c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?
   [ ] Yes; [X] No

   Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?
   [ ] Yes; [ ] No; [X] NA; if not, explain below

   d. Label requires an additional Storage and Disposal statement:

   [ ] Yes; [X] No; if yes explain below:

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7. Group **A**: Product Chemistry Data submitted

CITAB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	**Study Title**		**Data submitted**		**CITAB's Assessment of Data**	**MRID Nos. Cited**
			Yes	**No**		
830.1550	Product Identity & Composition		X		A	50194801
830.1600	Description of materials used to produce the product		X		A	50194801
830.1650	Description of formulation process		X		A	50194801
830.1670	Discussion on the formation of impurities		X		A	50194801
830.1700	Preliminary analysis			X	NA	
830.1750	Certified limits (158.350)	Standard certified limits	X		A	Revised Basic CSF dated 06-01-2017
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		X		A	50194802

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

8. Group **B:** Product chemistry data submitted

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos.
830.6303	Physical State	Liquid at 20°C	A	50194802
830.6315	Flammability	93.9°C	A	50194802
830.6316	Explodability	Non-explosive when submitted to heat and shock treatment	A	50194804
830.7000	pH	6.06 at 25°C (1% aqueous suspension)	A	50194802
830.7300	Density (units)	1.0477 g/cc (8.74 lbs/gal) at 20°C	A	50194802
830.7100	Viscosity	28.64 cps/20/ at 20°C 22.43 cps/20/ at 40°C	A	50194806 See Table below
830.6317	Storage stability	Stable in COEX containers when stored for 2 weeks at 54°C	A	50194802
830.6320	Corrosion characteristics	TS did not show any corrosive effects on the containers made of COEX when stored for 2 weeks at 54°C	A	50194802
830.6314	Oxidation/reduction	TS was found to be compatible with water, Zn dust, mono ammonium phosphate, potassium dichromate & turpentine	A	50194803

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830.7100: Viscosity Table under MRID No. 50194806

Table A Determination of viscosity by rotational viscometer at 20°C

Rotational speed (rpm)	Shear rates (sec^{-1})	Apparent viscosity (cP)
15.15	20	28.44 ± 0.12
22.73	30	27.62 ± 0.08
30.30	40	27.52 ± 0.10
22.73	30	28.07 ± 0.08
15.15	20	28.64 ± 0.30
Mean ±sd		**28.06 ± 0.49**

Table-B Determination of viscosity by rotational viscometer at 40°C

Rotational speed (rpm)	Shear rates (sec^{-1})	Apparent viscosity (cP)
15.15	20	22.50 ± 0.23
22.73	30	21.60 ± 0.40
30.30	40	21.44 ± 0.40
22.73	30	21.95 ± 0.33
15.15	20	22.43 ± 0.46
Mean ±sd		**21.98 ± 0.48**

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Waiver requests for group B product chemistry with MRID No. 50194807

Guideline No.	Title	Rationale for Waiver or Additional Information for Reference Guideline
830.6313	Stability to Normal and Elevated Temperatures, metals and ions	This product will not come into contact with metal containers or packaging. A storage stability and corrosion characteristics test was conducted at 54°C for two weeks and product was stable at test conditions. There were no changes in appearance of product or containers. *Reference: Storage Stability – 50194802*
830.6321	Dielectric breakdown voltage	This end use product does not have uses where the product would come into contact with electricity; therefore, it is requested that this requirement be waived. *Reference: 40 CFR 158.310 Product chemistry data requirements table.*
830.7050	UV/Visible Absorption	This is an end-use product formulation; therefore, these data are not required. *Reference: 40 CFR 158.310 Product chemistry data requirements table.*
830.7200	Melting Point	This is an end-use product formulation; therefore, these data are not required. *Reference: 40 CFR 158.310 Product chemistry data requirements table.*
830.7220	Boiling Point	This is an end-use product formulation; therefore, these data are not required. *Reference: 40 CFR 158.310 Product chemistry data requirements table.*
830.7370	Dissociation constant in water	This is an end-use product formulation; therefore, these data are not required. *Reference: 40 CFR 158.310 Product chemistry data requirements table.*
830.7520	Particle size, fiber diameter and particle distribution	This is an end-use product formulation; therefore, these data are not required. *Reference: 40 CFR 158.310 Product chemistry data requirements table.*
830.7550 830.7560 830.7570	Octanol Water Partition Coefficient	This is an end-use product formulation; therefore, these data are not required. *Reference: 40 CFR 158.310 Product chemistry data requirements table.*
830.7840 830.7860	Solubility in Water	This is an end-use product formulation, therefore these data are not required. *Reference: 40 CFR 158.310 Product chemistry data requirements table.*
830.7840 830.7860	Solubility in Organic Solvents	This is an end-use product formulation; therefore, these data are not required. *Reference: 40 CFR 158.310 Product chemistry data requirements table.*
830.7950	Vapor Pressure	This is an end-use product formulation; therefore, these data are not required. *Reference: 40 CFR 158.310 Product chemistry data requirements table.*

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CONCLUSIONS:

CITAB has reviewed the product chemistry data submitted for the end-use product and has concluded that:

A. Substantial similarity to the cited product (Reg. No. 100-1343) from Product chemistry view point

[X] Similar
[ ] Not similar, give reasons:
[ ] Not Applicable

B. **Confidential Statement of formula**

1. Revised Basic CSF (dated: 06-01-2017)
[X] Acceptable
[ ] Not Acceptable:
[ ] Not Applicable

2. Alternate CSF's (all dated:)
[ ] Acceptable
[ ] Not Acceptable:
[X] Not Applicable

C. Group A Product Chemistry Data

[X] Acceptable
[ ] Acceptable with the exception of the guideline:
[ ] Not acceptable
[ ] Not required
[ ] Data cited

D. Group B Product chemistry data

[X] Acceptable including waiver requests
[ ] Not acceptable
[ ] Acceptable with the exception of the guidelines:
[ ] Not required
[ ] Data cited for the guidelines

E. **Product Label/Draft Label:** Recommendations – Yes [ ]; No [X]